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SECTION VI

510(k) SUMMARY

NORMOCARB™ 25
Sterile Bicarbonate
Renal Dialysis Concentrate

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March 30, 2005

SECTION VI

510(k) Summary

NORMOCARB™ 25
Sterile Bicarbonate Renal Dialysis Concentrate

NAME OF DEVICE

Trade or Proprietary Name: NORMOCARB™ 25
(Sterile Bicarbonate Renal Dialysis Concentrate)

Classification Name: Hemodialysis Systems and Accessories
(dialysate concentrate for hemodialysis),
as per 21 CFR 876.5820.

Legally Marketed Device For Claim of Substantial Equivalence: NORMOCARB™ 35

DESCRIPTION AND INTENDED USE

NORMOCARB™ 25 is a clear, sterile, apyrogenic, calcium-free bicarbonate renal dialysis concentrate provided in 240 mL unit-dose vials which, when diluted with water in the required proportions, creates a dialysis solution or dialysate for use in hemodialysis.

Once prepared, the dialysate is indicated for use in Continuous Renal Replacement Therapy (CRRT), which is a dialysis continued 24 hours a day to treat critically ill patients with renal failure. CRRT is usually administered to patients in intensive care who require dialysis and are hemodynamically unstable, or whose liver function is either impaired or at risk of impairment. Patients with liver impairment typically are more challenging to manage and may have high requirements for bicarbonate due to ongoing lactic acidosis. The use of lactate-based solutions for dialysis may not correct metabolic acidosis if the liver cannot metabolize more lactate into bicarbonate. The bicarbonate-free, lactate-containing dialysis solution will actually remove some bicarbonate from the patient. In addition to a bicarbonate-based dialysis solution, patients with liver impairment and/or severe metabolic acidosis may require additional intravenous infusions of bicarbonate to maintain their pH within acceptable parameters.

The aims of CRRT are control of fluid balance, control of plasma electrolytes, control of acid-base balance and removal of products of metabolism.

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SUBSTANTIAL EQUIVALENCE

Dialysis Solutions Inc. (DSI) currently markets NORMOCARB™ 35 mEq/L in the United States for use in Continuous Renal Replacement Therapy which is a dialysis continued 24 hours a day. However, after the first 24 hours this concentrate becomes too much for these patients; and therefore DSI is seeking to add an additional strength of 25 mEq/L.

1) Summary Table

The following table summarizes the similarities and differences between NORMOCARB™ 25 mEq/L and 35 mEq/L Sterile Bicarbonate Renal Dialysis Concentrates.

Product Characteristic	(Currently Approved 6/30/00) Normocarb™ 35	PROPOSED NORMOCARB™ 25
Intended Use:	Dialysate concentrate for use in hemodialysis.	
Raw Materials:	All raw materials are tested to, and meet, USP standards.	
Components and Composition (Diluted):	Sodium: 140.0 mEq/L Magnesium: 1.5 mEq/L Chloride: 106.5 mEq/L Bicarbonate: 35.0 mEq/L	Sodium: 140.0 mEq/L Magnesium: 1.5 mEq/L Chloride: 116.5 mEq/L Bicarbonate: 25.0 mEq/L
Sterility:	NORMOCARB™ is manufactured as a sterile, pyrogen-free product.	
Container/ Closure:	The complete bicarbonate concentrate is packaged in clear, glass serum vials, closed with an elastomeric serum stopper and sealed with an aluminum crimp cap with a polypropylene cover.	
Diluent:	Sterile water – exceeds AAMI standards.	

2) Discussion

Intended Use:

Both NORMOCARB™ 25 and NORMOCARB™ 35 are bicarbonate-based dialysate concentrates for hemodialysis, as per 21 CFR 876.5820 Hemodialysis Systems and Accessories. Both products, when diluted, create a dialysate solution for use in renal dialysis therapy for the removal or delivery of compounds or electrolytes that the failing kidney cannot excrete or retain in the proper concentrations.

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SUBSTANTIAL EQUIVALENCE (Continued)

2) Discussion (Continued)

Intended Use: (Continued)

Both products are intended for use in Continuous Renal Replacement Therapy (CRRT), which is a dialysis continued 24 hours a day to treat critically ill patients in the intensive care unit. The following demonstrates the suitability of NORMOCARB™ 25 for the intensive care setting.

Components and Composition:

The raw materials of both NORMOCARB™ 25 and NORMOCARB™ 35 are tested to USP standards.

The diluted compositions of NORMOCARB™ 25 and NORMOCARB™ 35 are very similar, as demonstrated in the table on the previous page. The two products contain the same components, in comparable concentrations, with the exception of a slightly high level of chloride (116.5 mEq/L) and the lower level of bicarbonate (25.0 mEq/L) in the NORMOCARB™ 25 concentration.

The chloride level is slightly increased in order to maintain the same total concentration of anions and cations (mEq/L) in the reconstituted product. This increase in chloride is obtained by increasing the concentration of sodium chloride in NORMOCARB™ 35 by 7.89 g/L yielding a concentration of 0.726% w/v when reconstituted. Although this component is slightly increased, it is still below the maximum potency (0.8%) allowed for extracorporeal solutions in CDER's Inactive Ingredients Database thus safety of this slight increase is confirmed.

The bicarbonate levels are decreased to provide an additional lower strength of 25 mEq/L for CRRT patients, given that after the first 24 hours of treatment, the 35 mEq/L concentrate becomes too much for these patients. As this bicarbonate level is below that seen for NORMOCARB™ 35, any toxicity concerns of the component itself should be alleviated.

NORMOCARB™ 25, like NORMOCARB™ 35, is available as a complete concentrate containing all components, including the bicarbonate. The dialysate is prepared in a single-step process of dilution using 240 mL of NORMOCARB™ concentrate with 3 liters of sterile water to make 3.24 liters of dialysate.

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SUBSTANTIAL EQUIVALENCE (Continued)

2) Discussion (Continued)

Sterility:

Both NORMOCARB™ 25 and NORMOCARB™ 35 are sterile and pyrogen-free. While no bacteria can cross the dialysis membrane into blood, pyrogens can. Relatively stable patients in the chronic dialysis unit do not develop a severe reaction to small amounts of pyrogens, although there is more and more literature calling for very pure, and even sterile, solutions. A critically ill patient in the ICU setting, however, can be adversely affected by pyrogens and it is necessary to avoid the risk of pyrogens altogether in this setting. If a solution is not completely sterile there is a risk of release of pyrogens. Therefore, there is certain benefit to using a sterile dialysate, in particular for critically ill patients receiving dialysis treatment.

Container/Closure:

NORMOCARB™ 25 uses the same container/closure system as NORMOCARB™ 35. Both products are packaged in depyrogenated 240 mL clear glass serum vials, which are sealed with steam-sterilized gray, elastomeric serum stoppers and aluminum crimp caps with royal blue polypropylene covers.

A number of factors led to the use of 240 mL glass vials for the containment of NORMOCARB™. First and foremost, glass is well known for its inert and non-reactive qualities. Therefore, any reaction between the NORMOCARB™ concentrate and the glass vial, which could lead to the formation of undesired material in the product, is unlikely. This type of reactivity is more likely to occur with the use of plastic containers and, in addition, materials from the plastic itself can leach into the product. Glass is also much more effective than plastic as a barrier to adhesives and inks from labeling attached to, or printed on, the container.

Lastly, both products are available in a single-use quantity of 240 mL and is, therefore, less susceptible to product contamination than concentrates available in bulk, multi-use quantities.

Diluent:

Both NORMOCARB™ 25 and NORMOCARB™ 35 labeling instructs the user to dilute the concentrate using sterile water, a higher quality water than purified water or AAMI standard equivalent, in order to maintain the sterile quality of the NORMOCARB™ concentrate.

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SUBSTANTIAL EQUIVALENCE (Continued)

3) Conclusions

NORMOCARB™ 25 and NORMOCARB™ 35 are both bicarbonate renal dialysis concentrates with the same intended use and are very similar in composition (diluted). These similarities demonstrate the substantial equivalence of NORMOCARB™ 25 to NORMOCARB™ 35.

NORMOCARB™ 25 has a lower concentration of bicarbonate ions than NORMOCARB™ 35 while maintaining a concentration of anions and cations (mEq/L) that are equivalent to those in the approved formulation and that remain below the maximum potency allowed for extracorporeal solutions. This provides a lower strength formulation for the CRRT patient, which is as safe and effective as the approved formulation.

In addition, NORMOCARB™ 25 is manufactured as a sterile, pyrogen-free concentrate packaged in 240 mL single-use glass vials. The sterile quality of the product, the nature of the packaging materials, and the single-use fill volume (240 mL) provide for low risk of product contamination.

NORMOCARB™ 25 is available as a complete concentrate, including the bicarbonate, which requires only a single step of dilution with sterile water for preparation of the dialysate. These safety and convenience factors make NORMOCARB™ 25 ideally suited for its intended use for CRRT in the intensive care setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2005

Dialysis Solutions, Incorporated
c/o Mr. Kalpesh Shroff
Apotex Corporation
Project Leader – Regulatory Affairs
616 Heathrow Drive
LINCOLNSHIRE IL 60069

Re: K050827
Trade/Device Name: Normocarb™ 25 (Sterile Bicarbonate Renal Dialysis Concentrate)
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: July 20, 2005
Received: July 21, 2005

Dear Mr. Shroff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050827

Device Name: NORMOCARB™ 25 (Sterile Bicarbonate Renal Dialysis Concentrate)

Indications for Use:

NORMOCARB™ 25 Sterile Bicarbonate Renal Dialysis Concentrate, after dilution, is indicated for use as a dialysate, in Continuous Renal Replacement Therapy (CRRT).

Prescription Use X (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050827